

SEARCH REQUEST FORM

4-735

Examiner # (Mandatory): 76197 Requester's Full Name: Guilene A. Gabel
 Port Unit 1641 Location (Bldg/Room#): 7D16 CM1 Phone (circle 305 306 308) 0807
 Serial Number: 09/087871 Results Format Preferred (circle): PAPER DISK E-MAIL
 Title of Invention: Automated Diagnostic System Implementing
Immunoassays, Clinical Chemistry
 Inventors (please provide full names): Gerald Wagner Accdg to Reflex
Algorithm

Earliest Priority Date: 6-2-98

Keywords (include any known synonyms registry numbers, explanation of initialisms): (Analyzer @ Instrument Intern)

Diagnostic System: Immunassay Analyzer
Clinical Chemistry Analyzer
Hematology Analyzer } local processors

Processor = program = reflex algorithm
Network = private or public

(Biochemical/Biological) Marker measurement:
=> concentration level @ activity level
=> predetermined sequence of biochemical markers

(Automation/Automatic Execution)
Computer Program = first code - instruction
communication code

Search Topic:
 Please write detailed statement of the search topic, and the concept of the invention. Describe as specifically as possible the subject matter to be searched. Define any terms that may have a special meaning. Give examples of relevant citations, authors, etc., if known. You may include a copy of the abstract and the broadcast or most relevant claim(s).

See claim 1, 9, 10, 13, 16

Point of Contact:
 Beverly Shears
 Technical Info. Specialist
 CM1 12C14 Tel: 308-4994

STAFF USE ONLY

Searcher: Beverly C 4994 Type of Search _____ Vendors (include cost where applicable)
 Searcher Phone #: _____ N.A. Sequence ✓ SJN
 Searcher Location: _____ A.A. Sequence _____ Questel/Cbit
 Date Picked Up: _____ Structure (#) _____ Lexis/Nexis
 Date Completed: 05-05-99 Bibliographic _____ WWW/Internet
 Clerical Prep Time: 12 Litigation I _____ In-house sequence systems (list)
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 _____ Other _____ Westlaw
 _____ Other (specify) _____

BEST AVAILABLE COPY

Gabel, Gailene

To: STIC-ILL
Subject: 09/087,871

Please provide a copy of the following literature;

1) AZIZ D et al., REFLEXIVE ALGORITHMIC APPROACH TO CLINICAL DECISION-
MAKING - BREAST-CANCER AS A MODEL, JOURNAL OF CELLULAR BIOCHEMISTRY, (1993)
Supp. 17G, pp. 247.

Thanks a bunch,
Gailene R. Gabel
7B15
305-0807

POSTER ABSTRACTS

Quantitation of Estrogen and Progesterone Receptors by Immunocytochemical and Image Analyses

Douglas C. Aziz, MD, PhD and Raj R. Barathur, PhD

Specialty Laboratories, Inc., Santa Monica, CA 90404

Abstract The ability to detect estrogen and progesterone receptors by immunocytochemical analysis in formalin-fixed, paraffin-embedded sections has clear advantages over other techniques, including the ability to assay small biopsy specimens, fine needle aspirate samples, and archival material. Twenty-two cases of breast carcinoma were evaluated for estrogen and progesterone receptors by immunocytochemical analysis and enzyme immunoassay. Using a true color-based image analysis system, histograms of area versus the optical density of the positive staining nuclei were generated. A binary decision algorithm was derived from these histogram parameters by the Classification and Regression Trees (CART) computer program. Estimates generated by the algorithm for image analysis/immunocytochemical analysis had a 90% concordance with the enzyme immunoassay values. We conclude that quantitative immunocytochemical results for estrogen and progesterone receptor content in formalin-fixed, paraffin-embedded tissue can be generated using image analysis. © 1993 Wiley-Liss, Inc.

Reflexive Algorithmic Approach to Clinical Decision Making: Breast Cancer as a Model

Douglas C. Aziz, MD, PhD and Raj R. Barathur, PhD

Specialty Laboratories, Inc., Santa Monica, CA 90404

Abstract The number of tests available for the prognostication of patients with breast cancer, (e.g., estrogen and progesterone receptor, DNA ploidy, % S-phase analysis, HER-2/*neu*, EGFR, p53, cathepsin D, pS2, PCNA, etc.) is staggering. Many published studies statistically prove the prognostic significance for each independent test, but the situation becomes confusing and empirical for the clinician making a decision for a particular patient, particularly when test utilization and cost considerations must be weighed into the equation. Other factors such as the pathological stage, histological grade, vascular and lymphatic invasion, and the age and wishes of the patient should all be taken into consideration in arriving at the optimal treatment protocol. We have applied a Bayesian probability approach to published data in order to derive a branched tree algorithm to predict the survival rates for both lymph node-positive and lymph node-negative women with breast cancer. Specimen quality and test results suggested which subsequent tests were most clinically useful. The size of the algorithm was reduced to minimize the number of tests requested and thus reduce costs. This type of analysis is necessary to ensure that the most information is obtained at the lowest cost, and serves as a model for other diagnostic situations. © 1993 Wiley-Liss, Inc.